

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

RECEIVED  
02 AUG 2004

PCT

Applicant's or agent's file reference PCT 21023		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/18203	International filing date (day/month/year) 09 June 2003 (09.06.2003)	Priority date (day/month/year) 10 June 2002 (10.06.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): C07H 21/04; C12N 15/00, 1/20, 5/00 and US Cl.: 536/23.1, 23.2; 435/6, 15, 320.1, 325, 252.3			
Applicant MERCK & CO., INC.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ___ sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 07 January 2004 (07.01.2004)		Date of completion of this report 06 July 2004 (06.07.2004)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 872-9306		Authorized officer Padmavathi v Baskar <i>J. Roberts for</i> Telephone No. (571) 272-1600	

Form PCT/IPEA/409 (cover sheet)(July 1998)

Best Available Copy

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-96 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 97-99 as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages 1-4 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the sequence listing part of the description:  
pages 1-4 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>4, 11 and 18</u>	YES
	Claims <u>1-3, 5-10, 12-17</u>	NO
Inventive Step (IS)	Claims <u>4, 11 and 18</u>	YES
	Claims <u>1-3, 5-10, 12-17</u>	NO
Industrial Applicability (IA)	Claims <u>NONE</u>	YES
	Claims <u>1-18</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 4, 11 and 18 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a composition comprising the isolated and purified polypeptide SEQ.ID.NO: 2, an isolated purified polynucleotide comprising the polynucleotide sequence and an isolated and substantially purified encoded by the nucleotide sequence SEQ.ID.NO: 1.

Claims 1-3, 5-10 and 12-17 lack novelty under PCT Article 33(2) as being anticipated by Beraud et al or Moore et al disclose a purified polypeptide comprising an amino acid sequence SEQ.ID.NO: 13, and corresponding nucleic acid sequence SEQ.ID.NO: 30. The prior art protein and polynucleic acid sequences are 93.5% identical with the claimed polypeptide and polynucleic acid sequence because. The transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents openended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R01]. See Molecular Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open. for the inclusion of unspecified ingredients even in major amounts". On the other hand, the limitation "consisting of represents closed claim language and excludes any element, step, or ingredient not specified in the claim. In re Gray, 53 F. 2d 520, 11 USPQ 255 (CCPA 1931); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948). The prior art also teaches methods of modulating cell proliferation, methods of screening, method of inhibiting cell proliferation and method for detecting the polynucleic acid (see examples and claims). Thus the prior art anticipated the claimed invention.

Claims 1-18 lacks industrial applicability as defined by PCT Article 33(4) because human isolated polypeptides have not been shown to be useful for any industrial applicability as the peptides can be used for research purposes for studying the cellular proliferation etc.